NIST: The National Institute of Standards and Technology.

NVLAP: The National Voluntary Laboratory Accreditation Program. NVLAP is an Office within the National Institute of Standards and Technology.

Person: Associations, companies, corporations, educational institutions, firms, government agencies at the federal, state and local level, partnerships, and societies—as well as divisions thereof—and individuals.

Product: A type or a category of manufactured goods, constructions, installations, and natural and processed materials, or those associated services whose characterization, classification, or functional performance is specified by standards or test methods.

Proficiency testing: The determination of laboratory performance by means of comparing and evaluating calibrations or tests on the same or similar items or materials by two or more laboratories in accordance with predetermined conditions.

Quality manual: A document stating the quality policy, quality system, and quality practices of an organization. The quality manual may reference other laboratory documentation.

Quality system: The organizational structure, responsibilities, procedures, processes, and resources for implementing quality management.

Reference material: A material or substance one or more properties of which are sufficiently well established to be used for the calibration of an apparatus, the assessment of a measurement method, or for assigning values to materials. A ''certified reference material'' means that one or more of the property values of the reference material are certified by a technically valid procedure, accompanied by or traceable to a certificate or other documentation which is issued by a certifying body.

Reference standard: A standard, generally of the highest metrological quality available at a given location, from which measurements made at that location are derived.

Scope of accreditation: A document issued by NVLAP which lists the test methods or services, or calibration services for which the laboratory is accredited.

Sub-facility: A laboratory operating under the technical direction and quality system of a main facility that is accredited.

Test: A technical operation that consists of the determination of one or more characteristics or performance of a given product, material, equipment, organism, physical phenomenon, process or service according to a specified procedure.

Test method: A defined technical procedure for performing a test.

Testing laboratory: A laboratory which measures, examines, tests, calibrates or otherwise determines the characteristics or performance of products or materials.

Traceability of the accuracy of measuring instruments: A documented chain of comparison connecting the accuracy of a measuring instrument to other measuring instruments of higher accuracy and ultimately to a primary standard.

§ 285.6 NVLAP documentation.

NVLAP publications are available for information and use by staff of accredited laboratories, those seeking accreditation, other laboratory accreditation systems, and others needing information on the requirements for accreditation under the NVLAP program. Accredited laboratories will be sent revised publications routinely. Publications include:

(a) The Procedures and General Requirements, (15 CFR part 285);

(b) Handbooks containing the administrative and operational procedures and technical requirements of specific LAPs;

(c) A directory of accredited laboratories published annually and updated periodically; and

(d) Policy Guides that provide changes to the Procedures and General Requirements and Handbooks between formal revisions of those publications.

§ 285.7 Confidentiality.

To the extent permitted by applicable laws, NVLAP will seek to ensure confidentiality of all information obtained relating to the application, on-site assessment, proficiency testing,

evaluation, and accreditation of laboratories.

§ 285.8 Referencing NVLAP accreditation.

To become accredited and maintain accreditation, a laboratory shall agree in writing to:

(a) Follow NVLAP guidance when advertising its accredited status (including the use of the NVLAP logo) on letterheads, brochures, test reports, and professional, technical, trade, or other laboratory services publications.

(b) Inform its clients that the laboratory's accreditation or any of its calibration or test reports in no way constitutes or implies product certification, approval, or endorsement by NIST.

[59 FR 22747, May 3, 1994]

Subpart B—Establishing a LAP

§ 285.11 Requesting a LAP.

(a) A request to establish a LAP must be made to the Director of NIST.

(b) Each request must be in writing and must include:

(1) The scope of the LAP in terms of products, calibration services, or testing services proposed for inclusion;

(2) Specific identification of the applicable standards and test methods including appropiate designations, and the orgainizations or standards writing bodies having responsibility for them;

(3) A statement of need for the LAP including:

(i) Evidence of a national need to accredit calibration or testing laboratories for the specific scope beyond that served by an existing laboratory accreditation program in the public or private sector;

(ii) Evidence of a national need to accredit testing laboratories for the specific scope beyond that served by an existing laboriatory accreditation program in the public or private sector;

(iii) An estimate of the number of laboratories that may seek accreditation; and

(iv) An estimate of the number and nature of the users of such laboratories; and

(4) A stratement of the extent to which the requestor is willing to support necessary developmental aspects of the LAP with funding and personnel.

(c) NVLAP may request clarification of the information submitted according to paragraph (b) of this section.

(d) Before determining the need for a LAP, the Director of NIST shall publish a FEDERAL REGISTER notice of the receipt of a LAP request if the request complies with §7.11(b). The notice will:

(1) Describe the scope of the requested LAP;

(2) Indicate how to obtain a copy of the request; and

(3) State that anyone may submit comments on the need for a LAP to NVLAP within 60 days of the date of the notice.

(e) Following receipt of the identification of a mandate for a LAP based on legislative or administrative action, the Director shall publish a FEDERAL REGISTER notice:

(1) Stating the purpose of the LAP including the national or international need;

(2) Describing the general scope of the LAP;

(3) Identifying government agencies having oversight; and

(4) Providing information to any interested party wishing to be on the NVLAP mailing list to receive routine information on the development of the LAP.

(f) Consistent with applicable laws and regulations, the Director may negotiate and conclude agreements with the governments of other countries for NVLAP recognition of foreign laboratories. At a minimum, any agreement must provide that accredited foreign laboratories meet conditions for accreditation comparable to and consistent with those set out in these requirements.

[49 FR 44623, Nov. 8, 1984, as amended at 55 FR 38314, Sept. 18, 1990. Redesignated and amended at 59 FR 22747, May 3, 1994]

§ 285.12 LAP development decision.

(a) The Director of NIST shall establish all LAPs on the basis of need.

(1) A mandate to develop a LAP by NVLAP will be interpreted as a de facto decision to develop the specified LAP, and a LAP will be developed (or existing LAPs modified, if practical) following these procedures.